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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/574,995      | 03/06/2007  | David Jaramillo      | 1034381-000012      | 2187             |

41790 7590 12/30/2010  
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| EXAMINER |
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KOSACK, JOSEPH R

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

12/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| <b>Office Action Summary</b> | <b>Application No.</b><br>10/574,995 | <b>Applicant(s)</b><br>JARAMILLO ET AL. |  |
|                              | <b>Examiner</b><br>Joseph R. Kosack  | <b>Art Unit</b><br>1626                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8-12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 8-12,15,16 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,17 and 25 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 2, 4, 6, 8-12, and 14-25 are pending in the instant application.

#### ***Amendments***

The amendment filed on October 22, 2010 has been acknowledged and has been entered into the instant application file.

#### ***Previous Claim Objections***

Claim 14 was previously objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claim is still dependent on a rejected base claim, and the objection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 112***

Claims 1-7 and 17 were previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Applicant has traversed the rejection on the grounds that the amended claims contain the subject matter of claims 3, 5, and 7 and that the specification teaches a variety of different linkers to link pyrrole-imidazole polyamides and metal complexes.

The Examiner is not persuaded. Firstly, claims 3, 5, and 7 were previously rejected under 35 U.S.C. 112, first paragraph as lacking written description, so incorporating the subject matter from these claims is not enough on its own in order to overcome the rejection. The claims, as shown in the previous action, are drawn to a generic formula which is not adequately described by either chemical structure or a

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relative number of species. The species that are shown are drawn to an extremely narrow subgenus and not to the entire genus as claimed. Therefore, the Examiner must maintain the rejection for all of the claims except those expressly cancelled by the Applicant.

### ***Claim Objections***

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 17, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to compounds of the formula

$[M^1-T^1]_a-[P^1-T^1-M^1]_b-[T^1-P^1]_c$  where each P is a pyrrole-imidazole polyamide, each T is a linker group, and each M are metal coordination complexes. "a" can be 0 or 1, "b" can be 1, 2, 3, 4, or 5, and "c" can be 0, 1, or 2, leading to a number of different permutations of compounds.

The specification describes the terms in general terms. From the definitions on pages 2-3 of the specification, P group can comprise any number of imidazole and pyrrole rings, be linked by any group that comprises an amide functionality, the T group can be any type of linker group such as a covalent bond, an alkyl group, a ring, a functional group, etc..., and the M group can be any metal complex as long as one metal complex is capable of interacting with a major groove or minor groove of a polynucleotide. The nature of the interaction can be broad and does not required that any effect other than interaction, such as cell death, be capable by the metal complex.

The specification only details species of the extremely broad genus where: a is 0, b is 1, c is 0, P contains 3 or 4 total imidazole and pyrrole rings combined which are tethered together by -C(O)-NH- groups with the -C(O) attached at the 2-position of a ring and the NH- attached at the 4-position of a ring, the T group is a lower alkyl group, and the M complex is either a platinum or ruthenium complex as shown in the species of claim 14.

The Applicant is reminded of the written description guidelines set out by the USPTO in MPEP 2163:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

While the genus is described by a generic formula, the generic formula is not sufficiently detailed to show that the Applicant was in possession of the full scope of the claimed invention at the time of filing. Namely, that the definitions described above, while not being indefinite, are not sufficiently detailed in order to stand on their own as being adequately described. Therefore, the "representative number of species" standard is used to determine whether the claims are adequately described. MPEP 2163 goes on to describe what a "representative number of species" is:

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

The species described in the specification do not cover the entire genus such that it is a representative sample of the genus as the species are close together in structure and only describe an extremely small portion of the claimed genus. Therefore,

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the claims lack written description and are properly rejected under 35 U.S.C. 112, first paragraph.

### ***Conclusion***

Claims 1, 2, 4, 6, 17, and 25 are rejected. Claim 14 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/  
Primary Examiner, Art Unit 1626